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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/526,737	03/04/2005	Enrico Cinti	37891	7870

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EXAMINER

TRAN, SUSAN T

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 11/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/526,737

Applicant(s)

CINTI ET AL.

Examiner

Susan T. Tran

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 05/23/05.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ashmead et al. US 6,458,981 (Ashmead 1), in view of Ciribolla US 6,461,664 and Ashmead et al. US 4,020,158 (Ashmead 2).

Ashmead 1 teaches a composition and a method for preparing amino acid chelates that are essentially free of interfering ions. The composition is prepared by reacting a calcium oxide or hydroxide, an amino acid, and a soluble metal sulfate salt in an aqueous environment at a ratio sufficient to allow substantially all of the ions present in solution to react forming a positively charged metal amino acid chelate having a hydroxide counter ion, a calcium sulfate salt, and optionally, water (abstract and column 5, lines 55-60), metal amino acid chelate or amino acid chelate shall include metal ions bonded to ligands forming heterocyclic rings that can be coordinate covalent, covalent, and/or ionic at the carboxyl oxygen group (column 5, lines 20-25). Ashmead 1 also teaches the amino acid used are preferably one or more of the naturally occurring amino acid selected from the group consisting of methionine, alanine, arginine, asparagines, cysteine, glutamine, and combinations thereof (column 6, lines 15-20). Furthermore, Ashmead 1 teaches preferred metals and soluble metal sulfate salts.

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Suitable metals include such as copper, zinc, iron, cobalt, magnesium, manganese, chromium and combination thereof. Suitable soluble metal sulfate salts include copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2(\text{SO}_4)_3$], and combination thereof (column 6, lines 25-30).

Ciribolla teaches feed additive for agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal. The reaction is free from undesirable by-products, and the product is stable and effective in improving the main growth factors of the animals (abstract). The possible variants of a compound may be obtained by simply exchanging the bivalent metal (cuprous ion, zinc, manganous ion, cobalt, ferrous ion) chelated in each case with the organic molecule (column 4, lines 5-10).

Ashmead 2 teaches improvement of general health of animals by increasing the level of metals in biological tissues through the administration of multiple metals in the form of metal proteinates (abstract), protein hydrolysates are prepared in either acidic or basic media, unhydrolyzed protein salts, in general, pass through the intestine largely intact with only small amounts being utilized, therefore the protein molecules are hydrolyzed to a polypeptide, peptide or amino acid stage prior to mixing with a metal salt to form a proteinate (chelate with a protein hydrolysate as the ligand (column 3, lines 40-50). Ashmead 2 also teaches the metal proteinates are vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA

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and chelates formed from other ligands such as ascorbic or citric acids (column 4, lines 30-40).

Ashmead 1 teaches a composition and a method of preparing amino acid chelates by reacting a calcium oxide or hydroxide, an amino acid, and a soluble metal sulfate salt in an aqueous environment to form a positively charged metal amino acid chelate having a hydroxide counter ion, a calcium sulfate salt, and optionally, water; preferably one or more of the naturally occurring amino acid selected from the group consisting of methionine, alanine, arginine, asparagines, cysteine, glutamine, etc., and combinations thereof; and preferred metals and soluble metal sulfate salts; metals such as copper, zinc, iron, cobalt, magnesium manganese, chromium and combination thereof; soluble metal sulfate salts such as copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2(\text{SO}_4)_3$], and combination thereof. Ashmead 1 does not teach feed additive for agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal; improvement of animal health by increasing the levels of metals in biological tissues through the administration of multiple metals in the form of metal proteinates which can be prepared in either acidic or basic media, vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA and chelates formed from other ligands such as ascorbic or citric acids. However, Ashmead 2 teaches feed additive for agro-zootechnical use, in particular for alimentary

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use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal; improvement of animal health of by increasing the levels of metals in biological tissues through the administration of multiple metals in the form of metal proteinates which can be prepared in either acidic or basic media, vastly superior in being metabolically more assimilated in to the body compared to other chelates such as EDTA and chelates formed from other ligands such as ascorbic or citric acids. The prior arts recited as combined teach all the limitations of the instant claims. Therefore, It would have been deemed obvious to one having ordinary skill in the art at the time of the invention to select any of the calcium oxide or hydroxide, an amino acid such as methionine, alanine, arginine, metals such as copper, zinc, iron, cobalt, magnesium manganese, chromium and combination thereof; and soluble metal sulfate salts such as copper sulfate (CuSO_4), zinc sulfate (ZnSO_4), ferrous sulfate (FeSO_4), manganese sulfate (MnSO_4), cobalt sulfate (CoSO_4), magnesium sulfate (MgSO_4), ferric sulfate [$\text{Fe}_2(\text{SO}_4)_3$], chromic sulfate [$\text{Cr}_2(\text{SO}_4)_3$], and combination thereof to form a metal amino acid chelate having a hydroxide counter ion, a metal sulfate salt, and optionally, water for use in human or animal feeding. Thus the invention as whole has been prima face obvious to one of ordinary skill in the art at the time the invention was made.

Response to Arguments

Applicant's arguments filed 04/03/06 have been fully considered but they are not persuasive.

Applicant argues that Ashmead 1 does not teach or suggest:

1) that Methionine Hydroxy Analogue (MHA) can be used instead of the amino acid Methionine;

2) administering the integrator to human beings or animals suffering from deficiency of metal oligoelements;

3) a method in which an alkali metal or alkaline earth metal salt of MHA is reacted with a soluble iron (II) salt in water in a one step process; and

4) a composition comprising water and a complex of general formula as claimed in claims 33-35.

In response to applicant's arguments against Ashmead 1 individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Ashmead 1 is cited in view of the teachings of Ciribolla and Ashmead 2.

Furthermore, although claim 26 recites a "method for preparing an integrator", the claim does not recite any step requires to prepare the integrator. For examining purpose, claim 26 is interpreted as a composition claim until further clarification is submitted. Thus, the recitation "administering the integrator to human beings or animals suffering from deficiency of metal oligoelements" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble

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for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951). The method recited in claims 28 and 29 depends in the method of preparation in claim 26.

In response to applicant's argument regarding a one step process, it is noted that use of the transitional phrase "comprising of" recited in the claims do not preclude extra steps recited in the prior art.

Applicant argues that Ciribolla does not teach:

- 1) a method for preparing an integrator comprising at least one metal chelate;
- 2) that the integrator is administered the integrator to human beings or animals suffering from deficiency of metal oligoelements; and
- 3) that the integrator is administered to monogastric or polygastric animals.

In response to applicant's arguments against Ciribolla individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Furthermore, the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). Ciribolla is relied upon for the teachings of a feed additive for

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agro-zootechnical use, in particular for alimentary use in the zootechnical sector, consisting of a chelate obtained by the reaction of methionine hydroxyl analogue with the carbonate of bivalent metal. The reaction is free from undesirable by-products, and the product is stable and effective in improving the main growth factors of the animals (abstract). The possible variants of a compound may be obtained by simply exchanging the bivalent metal (cuprous ion, zinc, manganous ion, cobalt, ferrous ion) chelated in each case with the organic molecule (column 4, lines 5-10).

Applicant argues that Ashmead 2 does not teach or suggest:

1) the use of MHA at all.

However, Ashmead 2 is cited solely for the teaching of improving general health of animals by increasing the level of metals in biological tissues through the administration of multiple metals in the form of metal proteinates (abstract).

Pertinent Arts

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Burrington et al. teach a process for preparation of MHA or derivative and ester thereof. Koenig, Takano, Knodt, and Gordon teach feed supplement comprising MHA.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan T. Tran whose telephone number is (571) 272-0606. The examiner can normally be reached on M-F 6:00 am to 4:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in black ink, appearing to read 'S. Tran', with a stylized, cursive flourish extending from the end.

S. Tran
Primary Examiner
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